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South Australia

Controlled Substances (Poisons) (Electronic Prescriptions) Variation Regulations 2020

under the *Controlled Substances Act 1984*

Contents

Part 1—Preliminary

1—Short title

These regulations may be cited as the *Controlled Substances (Poisons) (Electronic Prescriptions) Variation Regulations 2020*.

2—Commencement

These regulations come into operation on the day on which they are made.

3—Variation provisions

In these regulations, a provision under a heading referring to the variation of specified regulations varies the regulations so specified.

Part 2—Variation of *Controlled Substances (Poisons) Regulations 2011*

4—Variation of regulation 3—Interpretation

(1) Regulation 3(1)—after the definition of ***address*** insert:

approved electronic communication means an electronic communication of a kind approved from time to time by the Minister;

approved electronic form, in relation to a prescription for a drug, means—

(a) a form approved from time to time by the Secretary under the Commonwealth Regulations; or

(b) a form approved from time to time by the Minister,

for the giving of prescriptions for drugs in electronic form;

approved information technology requirements means information technology requirements approved from time to time by the Minister;

(2) Regulation 3(1)—after the definition of ***Chief Executive*** insert:

Commonwealth Regulations means the *National Health (Pharmaceutical Benefits) Regulations 2017* of the Commonwealth;

(3) Regulation 3(1)—after the definition of ***drug*** insert:

electronic communication has the same meaning as in the *Electronic Communications Act 2000*;

electronic prescription means a prescription given in an approved electronic form;

(4) Regulation 3(1)—after the definition of ***health service facility*** insert:

information technology requirements has the same meaning as in the *Electronic Communications Act 2000*;

(5) Regulation 3(1), definition of ***medication chart prescription***—delete the definition and substitute:

medication chart prescription has the same meaning as in the Commonwealth Regulations;

5—Substitution of regulation 33

Regulation 33—delete the regulation and substitute:

33—How prescriptions are to be given

(1) Subject to this regulation, a prescriber must give a prescription for a drug—

(a) in writing; or

(b) in an approved electronic form.

Maximum penalty: $5 000.

(2) A prescriber may, if of the opinion that good reason exists for doing so, give a prescription for a drug to a pharmacist by—

(a) telephone; or

(b) fax; or

(c) an approved electronic communication.

(3) If a prescriber gives a prescription in writing, the prescriber must give the prescription to—

(a) in the case of a prescription for a drug for human use—

(i) the person for whom the drug is to be supplied; or

(ii) a person acting on behalf of the person for whom the drug is to be supplied; or

(b) in the case of a prescription for a drug for animal use—

(i) the owner of the animal; or

(ii) a person acting on behalf of the owner of the animal.

Maximum penalty: $5 000.

(4) If a prescription is given in an approved electronic form, the prescriber must—

(a) in the case of a prescription in a form approved by the Secretary under the Commonwealth Regulations—prepare and submit the prescription in accordance with any approved information technology requirements (as defined in the Commonwealth Regulations) by means of an eligible electronic communication (as defined in the Commonwealth Regulations); or

(b) in the case of a prescription in a form approved by the Minister—prepare and submit the prescription in accordance with approved information technology requirements (if any) by means of an approved electronic communication.

Maximum penalty: $3 000.

(5) If a prescription is prepared in an approved electronic form, the prescriber must include in the prescription—

(a) the date on which the prescription is given; and

(b) the prescriber's professional name, address and telephone number; and

(c) the full name and address of the person for whom the prescription is intended; and

(d) the name, dose form and (if relevant) the route of administration of the drug being prescribed; and

(e) if applicable—the strength of the drug being prescribed; and

(f) the dose of the drug to be administered to the person for whom the drug is being prescribed; and

(g) the frequency at which the drug is to be administered; and

(h) the total amount of the drug to be supplied each time the prescription is dispensed; and

(i) the total number of times the drug may be dispensed; and

(j) if the prescription is for a drug of dependence for human use—the date of birth of the person for whom the prescription is intended; and

(k) the words—

(i) "For dental treatment only" if the prescriber is a dentist; or

(ii) "For podiatric treatment only" if the prescriber is a podiatrist; or

(iii) "For animal treatment only" if the prescriber is a veterinary surgeon.

Maximum penalty: $3 000.

(6) If a prescription for a drug of dependence is prepared in an approved electronic form, the prescriber must keep a record of all the details required by subregulation (5) to be included in the prescription.

Maximum penalty: $3 000.

(7) If a prescription is given to a pharmacist by telephone, the prescriber must give the pharmacist—

(a) the prescriber's professional name, address and telephone number; and

(b) the full name and address of the person for whom the prescription is intended (or, if the prescription is intended for an animal, the species of animal for which it is intended, the name and address of the owner of the animal and the name (if any) of the animal); and

(c) the name, dose form and (if relevant) the route of administration of the drug being prescribed; and

(d) if applicable—the strength of the drug being prescribed; and

(e) the dose of the drug to be administered to—

(i) the person for whom the drug is being prescribed; or

(ii) the animal in relation to which the drug is being prescribed,

(as the case may be);

(f) the total amount of the drug to be supplied; and

(g) the frequency at which the drug is to be administered; and

(h) if the prescription is for a drug of dependence for human use—the date of birth of the person for whom the prescription is intended.

Maximum penalty: $3 000.

(8) If a prescription is given to a pharmacist by telephone—

(a) the prescriber must, immediately after so giving the prescription, complete a prescription in writing that—

(i) clearly states that it is given in confirmation of the prescription given by telephone on the particular date on which it is so given; and

(ii) otherwise complies with these regulations; and

(b) the prescriber must forward the written prescription to the pharmacist—

(i) if the prescription is for a drug of dependence—within 24 hours of giving the prescription by telephone; or

(ii) in any other case—as soon as practicable after giving the prescription by telephone.

Maximum penalty: $3 000.

(9) If a prescription is given to a pharmacist by fax, the prescriber must forward the original prescription to the pharmacist—

(a) in the case of a prescription for a drug of dependence—within 24 hours of giving the prescription by fax; or

(b) in any other case—as soon as practicable after giving the prescription by fax,

unless the prescriber has endorsed the prescription given by fax with the name and address of a single pharmacy at which the prescription may be dispensed.

Maximum penalty: $3 000.

(10) If a prescription is given to a pharmacist by an approved electronic communication, the prescriber must comply with any requirements imposed by the Minister.

Maximum penalty: $3 000.

(11) This regulation does not apply to a prescriber who gives a prescription for a drug if—

(a) the prescription is a medication chart prescription; and

(b) the provisions of the Commonwealth Regulations applying to the giving of a medication chart prescription for a pharmaceutical benefit are complied with in relation to the giving of the prescription of the drug (whether or not the drug is a pharmaceutical benefit).

6—Variation of regulation 34—Written prescriptions

(1) Regulation 34(3)—delete subregulation (3)

(2) Regulation 34(4)—delete "*National Health (Pharmaceutical Benefits) Regulations 2017* of the Commonwealth" and substitute:

Commonwealth Regulations

7—Substitution of regulations 35 and 35A

Regulation 35—delete the regulation and substitute:

35—Dispensing prescriptions

(1) If a pharmacist or medical practitioner dispenses a drug pursuant to a prescription, the pharmacist or medical practitioner must—

(a) in the case of a written prescription or electronic prescription—record in or on the prescription—

(i) the pharmacist's or medical practitioner's name, business name (if any) and business address; and

(ii) the date on which the drug is dispensed; and

(iii) the unique identifier applicable to the drug; or

(b) in the case of a prescription given by fax that is endorsed with the name and address of a single pharmacy at which the prescription is to be dispensed—endorse on the faxed copy—

(i) the pharmacist's or medical practitioner's name, business name (if any) and business address; and

(ii) the date on which the drug is dispensed; and

(iii) the unique identifier applicable to the drug.

Maximum penalty: $5 000.

(2) A pharmacist or medical practitioner who dispenses a drug pursuant to a prescription must, on the day on which the drug is dispensed, record the following information:

(a) the unique identifier applicable to the drug dispensed on the prescription;

(b) the name of the pharmacist or medical practitioner as the dispenser;

(c) the date on which the drug is dispensed;

(d) the trade name or the approved name of the drug, or, if it does not have either a trade or approved name, the ingredients of the drug;

(e) if the drug is dispensed for a person—

(i) the full name and address of the person; and

(ii) in the case of a drug of dependence—the person's date of birth;

(f) if the drug is intended for an animal—the species of animal for which it is intended, the name and address of the owner of the animal and the name (if any) of the animal;

(g) the form, strength and quantity of the dispensed drug;

(h) the directions given for the safe and proper use of the dispensed drug;

(i) the name, address and business telephone number of the person who prescribed the drug;

(j) the number of times the prescription may be dispensed and (if the prescription so specifies) the intervals at which the drug may be dispensed;

(k) any instructions the prescriber has included in or on the prescription in relation to a specialised supply of the drug;

(l) if the prescription is endorsed for dispensing at a single pharmacy—the name and address of that pharmacy.

Maximum penalty: $5 000.

(3) A pharmacist or medical practitioner must not do the following:

(a) in the case of a prescription for an S4 poison that does not specify the number of times the drug is to be dispensed—dispense the drug more than once pursuant to the prescription;

(b) in the case of a prescription that specifies the number of times and the intervals at which the drug may be dispensed—dispense the drug more times than the number specified or at intervals less than those specified;

(c) in the case of a prescription that specifies the number of times, but not the intervals at which, the drug may be dispensed—dispense the drug more frequently than the pharmacist or medical practitioner considers appropriate.

Maximum penalty: $5 000.

(4) Despite subregulation (3)(b), if a pharmacist or medical practitioner is satisfied that a person—

(a) has lost a previously dispensed supply of a drug; or

(b) will, through absence from the State or otherwise, find it unduly difficult to have future supplies of a drug dispensed as needed,

the pharmacist or medical practitioner may (but is not obliged to) dispense a prescription for the person at an interval earlier than that specified in or on the prescription.

(5) If, under subregulation (4), a pharmacist or medical practitioner dispenses a drug of dependence at an earlier interval than that specified in or on the prescription, the pharmacist or practitioner must notify the prescriber of that fact in writing.

Maximum penalty: $5 000.

(6) If a prescription given by fax is endorsed with the name and address of a single pharmacy at which the drug may be dispensed, a pharmacist must not dispense the drug unless the pharmacist is on duty at that pharmacy.

Maximum penalty: $5 000.

(7) A pharmacist or medical practitioner must not dispense a drug if—

(a) the prescription for the drug—

(i) is presented or otherwise sought to be dispensed—

(A) in the case of a drug of dependence—more than 6 months after the date on which it was written; or

(B) in any other case—more than 12 months after the date on which it was written; or

(ii) has been cancelled; or

(iii) is partly or wholly illegible; or

(iv) does not comply with the Act or these regulations; or

(b) there are reasonable grounds for suspecting that the prescription has been altered, forged or obtained by false pretenses.

Maximum penalty: $5 000.

(8) If a prescription for a drug that is to be dispensed for the first or only time is given in writing, a pharmacist or medical practitioner must not dispense the drug unless the original written prescription for the drug is presented to the pharmacist or medical practitioner.

Maximum penalty: $5 000.

(9) If a prescription for a drug that is to be dispensed for the first or only time is given by fax, a pharmacist or medical practitioner must not dispense the drug unless the faxed prescription is endorsed with the name and address of a single pharmacy at which the drug may be dispensed.

Maximum penalty: $5 000.

(10) If a prescription for a drug that is to be dispensed for the second or subsequent time is given in writing, a pharmacist or medical practitioner must not dispense the drug unless—

(a) the original written prescription for the drug and a written record (whether made on the prescription or on a separately attached repeat authorisation) of the number of times the drug has been dispensed are presented to the pharmacist or medical practitioner; or

(b) a duplicate or copy of the written prescription for the drug and a written record (made both on the duplicate or copy (as the case may be) and on a separately attached repeat authorisation) of the number of times the drug has been dispensed are presented to the pharmacist or medical practitioner.

Maximum penalty: $5 000.

(11) If a pharmacist or medical practitioner—

(a) dispenses a drug pursuant to a written prescription; and

(b) the drug is fully dispensed,

the pharmacist or medical practitioner must endorse the prescription with the word "CANCELLED" on the day on which the drug is dispensed.

Maximum penalty: $5 000.

(12) If a pharmacist—

(a) dispenses a drug pursuant to a prescription given by fax that is endorsed with the name of a single pharmacy at which the prescription may be dispensed; and

(b) the drug is fully dispensed,

the pharmacist must endorse the faxed copy of the prescription with the word "CANCELLED" on the day on which the drug is dispensed.

Maximum penalty: $5 000.

(13) If a pharmacist or medical practitioner—

(a) dispenses a drug pursuant to an electronic prescription; and

(b) the drug is fully dispensed,

the pharmacist or medical practitioner must record in or on the prescription, on the day that the prescription is dispensed, that the prescription is cancelled.

(14) A pharmacist or medical practitioner who dispenses a prescription for an S4 poison must, unless the prescription is for any reason forwarded to the Department or the Minister—

(a) in the case of a written prescription—

(i) retain the original or duplicate prescription for at least 1 year; and

(ii) keep the original or duplicate prescription readily available for inspection by an authorised officer during that period; or

(b) in the case of a prescription given by fax—

(i) retain the faxed copy of the prescription for at least 1 year; and

(ii) keep the faxed copy of the prescription readily available for inspection by an authorised officer during that period; or

(c) in the case of an electronic prescription—

(i) retain the electronic prescription or a computer-generated printed copy of it for at least 1 year; and

(ii) keep the electronic prescription or a computer-generated printed copy of it readily available for inspection by an authorised officer during that period.

Maximum penalty: $5 000.

(15) If a prescription has been issued in duplicate and the original is retained by the pharmacist or medical practitioner, it is sufficient compliance with this regulation if the required information is marked on the duplicate prescription.

(16) For the purposes of this regulation—

(a) a prescription for a drug is ***fully dispensed*** if—

(i) in the case of a prescription authorising dispensing of the drug once only—the drug has been dispensed on 1 occasion; or

(ii) in the case of a prescription authorising dispensing of the drug more than once—the drug has been dispensed for the last time;

(b) an electronic prescription for a drug is ***presented*** when it is accessed electronically by a pharmacist or medical practitioner for the purpose of dispensing the drug.

(17) This regulation (other than subregulations (2), (7)(a) and (7)(b)) does not apply to a pharmacist or medical practitioner who dispenses a drug on a prescription if—

(a) the prescription is a medication chart prescription; and

(b) the provisions of the Commonwealth Regulations applying to the sale or supply of a pharmaceutical benefit have been complied with in relation to the sale or supply of the drug (whether or not the drug is a pharmaceutical benefit).

35A—Dispensing prescriptions for drugs of dependence—special provisions

(1) A pharmacist who dispenses a drug of dependence on prescription must—

(a) each time that the drug is dispensed—make a record in electronic form that complies with regulation 35(2); and

(b) transmit that record electronically to the Chief Executive so that it is received no later than the 7th day of the month following the month in which the drug was dispensed (or such later day as the Chief Executive may, on the application of the pharmacist, authorise).

Maximum penalty: $5 000.

(2) A pharmacist in charge of a pharmacy at which no drugs of dependence are dispensed for a period of 30 consecutive days must, no later than the 7th day of the month following the month during which the 30th day of that period falls, notify the Chief Executive of that fact in writing.

Maximum penalty: $5 000.

(3) A pharmacist or medical practitioner who dispenses a drug of dependence on prescription must—

(a) in the case of a written prescription—

(i) retain the original prescription or a copy of the prescription for at least 2 years; and

(ii) keep it readily available for inspection by an authorised officer during that period; and

(iii) on request by an authorised officer—send a copy of the prescription to the authorised officer; or

(b) in the case of a prescription given by fax—

(i) retain the faxed copy of the prescription for at least 2 years; and

(ii) keep the faxed copy of the prescription readily available for inspection by an authorised officer during that period; and

(iii) on request by an authorised officer—send a copy of the faxed copy of the prescription to the authorised officer; or

(c) in the case of an electronic prescription—

(i) retain the electronic prescription or a computer-generated printed copy of it for at least 2 years; and

(ii) keep the electronic prescription or a computer-generated printed copy of it readily available for inspection by an authorised officer during that period; and

(iii) on request by an authorised officer—send a computer-generated printed copy of the electronic prescription to the authorised officer.

Maximum penalty: $5 000.

(4) A pharmacist or medical practitioner must not—

(a) dispense more than 2 days supply of a drug of dependence unless at least 1 of the following applies:

(i) the person for whose use the drug is prescribed is known to the pharmacist or practitioner;

(ii) the pharmacist or practitioner recognises the signature on the prescription as that of the prescriber who purportedly gave the prescription;

(iii) the pharmacist or practitioner has verified with the prescriber who purportedly gave the prescription that the prescription was in fact given by that prescriber; or

(b) hand over a drug of dependence dispensed by the pharmacist or medical practitioner until—

(i) the person for whose use the drug is dispensed—

(A) has signed and dated the prescription or, if the prescription was given by fax, the faxed copy of the prescription; and

(B) has, unless the person is known to the pharmacist or practitioner, produced satisfactory evidence of his or her identity; or

(ii) the person for whose use the drug is dispensed—

(A) has signed a computer-generated printed copy of the prescription that includes all the information required to be provided on a written prescription; and

(B) has, unless known to the pharmacist or practitioner, produced satisfactory evidence of his or her identity; or

(iii) an agent acting on behalf of the person for whose use the drug is intended—

(A) has signed and dated the prescription or, if the prescription was given by fax, the faxed copy of the prescription; and

(B) has, unless the agent is known to the pharmacist or practitioner, produced satisfactory evidence of his or her identity; or

(iv) an agent acting on behalf of the person for whose use the drug is intended—

(A) has signed a computer-generated printed copy of the prescription that includes all the information required to be provided on a written prescription; and

(B) has, unless known to the pharmacist or practitioner, produced satisfactory evidence of his or her identity.

Maximum penalty: $5 000.

(5) This regulation (other than section 35A(3)) does not apply to a pharmacist or medical practitioner who dispenses a drug of dependence on prescription if—

(a) the prescription is a medication chart prescription; and

(b) the provisions of the Commonwealth Regulations applying to the sale or supply of a pharmaceutical benefit have been complied with in relation to the sale or supply of the drug (whether or not the drug is a pharmaceutical benefit).

Note—

As required by section 10AA(2) of the *Subordinate Legislation Act 1978*, the Minister has certified that, in the Minister's opinion, it is necessary or appropriate that these regulations come into operation as set out in these regulations.

Made by the Governor

after consultation by the Minister with the Controlled Substances Advisory Council and with the advice and consent of the Executive Council
on 18 June 2020

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